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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,038	08/09/2001	Hisatomi Ito	NANP110US	4720

23623 7590 12/18/2002

AMIN & TUROCY, LLP
1900 EAST 9TH STREET, NATIONAL CITY CENTER
24TH FLOOR,
CLEVELAND, OH 44114

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/927,038	Applicant(s) ITO ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11 and 12* is/are allowed.

6)☒ Claim(s) *1-3,6-10 and 13* is/are rejected.

7)☒ Claim(s) *4,5,14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-15 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Dec. 3, 2001 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or **use** the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of preventing neurodegenerative diseases such as Alzheimer's disease comprising administering citrus extracts or polyalkoxyflavonoid compounds.

(2) The state of the prior art

While the art recognizes the treatment of neurodegenerative diseases such as Alzheimer's disease, (please see art relied upon in the rejection), the art does not recognize, however, therapeutic remedies which result in the complete prevention of said diseases.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are broad and encompass numerous neurodegenerative conditions or diseases including Alzheimer's disease.

(6) The amount of direction or guidance presented

Applicant's specification provides guidance for and is only enabled for the use of polyalkoxyflavonoid compounds for extending neurites and thus for the treatment of neurodegenerative disorders. However, the specification provides no guidance, in the way of written description, to enable one of ordinary skill in the art to prevent neurodegenerative diseases such as Alzheimer's disease. Applicant's specification does not enable one of ordinary

skill in the art to use compositions containing polyalkoxyflavonoid compounds in the prevention of such disorders.

(7) The presence or absence of working examples

The examples in Applicant's specification describe using polyalkoxyflavonoid compounds (in extracts) for extending neurites from cells isolated from rats. Please see Example 4.

(8) The quantity of experimentation necessary

Since prevention of neurodegenerative diseases such as Alzheimer's disease has not been achieved and thus recognized in the art, and since Applicant's specification only provides data for inducing neurite growth in cells isolated from rats, one of ordinary skill in the art would be burdened with undue experimentation to determine the pharmacological parameters i.e. dosage, etc. necessary to enable one of ordinary skill in the art to actually prevent the occurrence of neurodegenerative diseases such as Alzheimer's disease.

The Examiner respectfully suggests cancelling "preventing" from the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, or (2) a patent granted on an application for patent by another filed in

> the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 3 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Obukowicz et al., US 2001/0024664 A1.

Obukowicz et al. disclose the invention substantially as claimed. Specifically, Obukowicz et al. disclose a method for treating central nervous system disorders such as cortical dementias including Alzheimer's disease comprising administering to a person in need thereof an effective amount of a plant extract such as an extract from the citrus family. Please see [0006]; [0019]; [0020]; [0072]; Tables 4 and 5.

The claims are anticipated by Obukowicz et al. because Obukowicz et al. teach administering an identical extract, i.e. citrus extract, to a host using Applicant's claimed method steps. Accordingly, extension of neurite growth and prevention of neurodegenerative diseases would be inherent.

3. Claims 1, 2, 6, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wenzel et al., US 2001/0046963 A1.

Wenzel et al. disclose a method for treating Alzheimer's disease comprising administering effective amounts of a compound, i.e. tangeretine. Please see [0001]; [0024]; [0056].

The claims are anticipated by Wenzel et al. because Wenzel et al. disclose administering an identical compound, i.e. tangeretine, to a host using Applicant's claimed method steps.

Accordingly, extension of neurite growth and prevention of neurodegenerative diseases would be inherent.

4. Claims 1, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Castillo et al., US 2001/0047032 A1.

Castillo et al. teach a method for treating Alzheimer's disease or Parkinson's disease by administering effective amounts of a compound gardenin B to a patient in need thereof. Please see the abstract; claims 1 and 29; [0036].

The claims are anticipated by Castillo et al. because Castillo et al. disclose administering an identical compound embraced by Applicant's formula, i.e. Gardenin B, to a host using Applicant's claimed method steps. Accordingly, extension of neurite growth and prevention of neurodegenerative diseases would be inherent.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 8-81382 (submitted by Applicant). wld

JP 8-81382 discloses a method of orally administering to a host an extract (juice, powders) from a plant belonging to the citrus family. Please see partial translation submitted by Applicant.

The claims are anticipated by JP 8-81382 because JP 8-81382 teaches administering an identical extract, i.e. citrus extract, to a host using Applicant's claimed method steps.

Accordingly, extension of neurite growth and prevention of neurodegenerative diseases would be inherent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 8-81382, supra and Lanzendorfer et al., 6,423,747.

JP 8-81382 as applied above. In addition to oral administration of the citrus extracts, JP 8-81382 discloses topical administration to the skin (dermatological composition). Please see the English translation.

Lanzendorfer et al., disclose dermatological preparations containing flavonoids, wherein citrus extracts may be used in the dermatological preparations. Moreover, Lanzendorfer et al. disclose that the skin is equipped with merker cell-neurite complexes. Please see col. 2, lines 52-54; col. 7, lines 23-29.

Therefore, extension of neurite growth would be obvious in the methods of JP 8-81382 and Lanzendorfer et al. because both JP 8-81382 and Lanzendorfer disclose contacting neurites which are present in the skin with identical compositions containing citrus extracts.

Allowable Subject Matter

Claims 11-12 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed methods.

9. Claims 4, 5, 14, 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-3, 6-10, 13 are rejected.

Claims 4, 5, 14, 15 are objected to.

Claims 11-12 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Dec. 14, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600